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Attorneys for Plaintiffs Genentech, Inc. and Curis, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GENENTECH, INC. and CURIS, INC. Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES LTD. and SUN PHARMACEUTICAL INDUSTRIES, INC. Defendants.	Civil Action No. _____ (Filed Electronically)

COMPLAINT

Plaintiffs Genentech, Inc. ("Genentech") and Curis, Inc. ("Curis") (collectively, "Plaintiffs"), by their attorneys, for their Complaint, allege as follows:

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 et seq., which arises out of the submission by Sun Pharmaceutical Industries, Ltd. (Sun Ltd.) and Sun Pharmaceutical Industries, Inc. (Sun Inc., and collectively with Sun Ltd., "Sun") of Abbreviated New Drug Application ("ANDA") No. 220393 to the U.S. Food and Drug Administration ("FDA") seeking approval to commercially manufacture, use, offer for

sale, sell, and/or import generic versions of Plaintiffs' ERIVEDGE® (vismodegib) capsule, 150 mg, prior to the expiration of U.S. Patent No. 9,278,961 ("the '961 Patent").

PARTIES

Plaintiffs

2. Plaintiff Genentech, Inc. is a company organized under the laws of the State of Delaware with its principal place of business at 1 DNA Way, South San Francisco, CA 94080.

3. Plaintiff Curis, Inc. is a company organized under the laws of the State of Delaware with its principal place of business at 128 Spring Street, Building C - Suite 500, Lexington, MA 02421.

Defendants

4. On information and belief, Defendant Sun Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (East), Mumbai, Maharashtra, 400063, India and a registered address at Sun Pharma Advanced Research Centre (SPARC), Tandalja, Vadodara City, Vadodara District, Gujarat, India.

5. On information and belief, Sun Ltd. is the fourth largest specialty generic pharmaceutical company in the world. On information and belief, Sun Ltd., in concert with and through the actions of its subsidiaries, including Sun Inc., operates as a generics pharmaceutical company in the United States and is in the business of, among other things, developing, manufacturing, obtaining regulatory approval for, marketing, distributing, and selling generic pharmaceutical products in New Jersey and throughout the United States. Sun Ltd.'s website (https://sunpharma.com/usa/) characterizes itself as "a leading player in the generics market in the U.S." and states that its "U.S. headquarters is in Princeton, New Jersey."

6. Sun Ltd. is the owner of ANDA No. 220393.

7. On information and belief, Defendant Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of the State of Delaware, having a place of business at 2 Independence Way, Princeton, New Jersey 08540, and another place of business at 1 Commerce Drive, Cranbury, New Jersey 08512. Upon information and belief, Sun Inc. is headquartered in Princeton, New Jersey.

8. Upon information and belief, Sun Inc. is a wholly owned subsidiary of Sun Ltd., and is controlled and dominated by Sun Ltd. On information and belief, Sun Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs for sale throughout the United States, including throughout the State of New Jersey.

9. On information and belief, Sun Ltd., acting in concert with Sun Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Sun Ltd., acting in concert with Sun Inc., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

10. On information and belief, Sun knows and intends that upon approval of Sun's ANDA, Sun will manufacture and directly or indirectly market, sell, and distribute Sun's vismodegib capsules ("Sun's ANDA Product") throughout the United States, including in New Jersey.

11. On information and belief, Sun Ltd. and Sun Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into New Jersey, and including with respect to Sun's ANDA Product at issue.

12. On information and belief, following any FDA approval of Sun's ANDA, Sun Ltd. and Sun Inc. will act in concert to market, distribute, offer for sale, and sell Sun's ANDA Product throughout the United States and within New Jersey.

13. On information and belief, following any FDA approval of Sun's ANDA, Sun knows and intends that Sun's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within New Jersey.

JURISDICTION

14. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

15. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a); 28 U.S.C. §§ 2201 and 2202 and 35 U.S.C. § 1 *et seq*.

16. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over Sun Ltd. and Sun Inc.

17. This Court has personal jurisdiction over Sun Inc. because, among other things, Sun Inc. has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. Sun Inc. is a company with a principal place of business in New Jersey. On information and belief, Sun Inc. develops,

manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey. It therefore has consented to general jurisdiction in New Jersey.

18. On information and belief, Sun Inc. is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in New Jersey, and relies on contributions from Sun Ltd.

19. On information and belief, Sun Inc., acting as the agent of Sun Ltd., markets, distributes, offers for sale, and/or sells in New Jersey and elsewhere in the United States generic pharmaceutical products that are manufactured by Sun Ltd. or for which Sun Ltd. is the named applicant on approved ANDAs.

20. This Court has personal jurisdiction over Sun Ltd. because, among other things, Sun Ltd. has purposefully availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Sun Ltd. develops, manufactures, imports, markets, offers to sell, sells, and/or imports generic drugs throughout the United States, including in New Jersey, and therefore transacts business within New Jersey, and/or has engaged in systematic and continuous business contacts within New Jersey.

21. In addition, this Court has personal jurisdiction over Sun Ltd. and Sun Inc. because, among other things, on information and belief: (1) Sun Ltd. and Sun Inc. acted in concert to file Sun's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product in the United States, including in New Jersey; and (2) Sun Ltd. and Sun Inc., acting in concert and/or as agents of one another,

will market, distribute, offer for sale, sell, and/or import Sun's ANDA Product in the United States, including in New Jersey, upon approval of Sun's ANDA, and will derive substantial revenue from the use or consumption of Sun's ANDA Product in New Jersey. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016). On information and belief, upon approval of Sun's ANDA, Sun's ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

22. In addition, this Court has personal jurisdiction over Sun Ltd. and Sun Inc. because Sun Ltd. and Sun Inc. regularly (1) engage in patent litigation concerning FDA approved branded drug products in this District, (2) do not contest personal jurisdiction in this District, and (3) purposefully avail themselves of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Sun Pharma. Indus. Ltd. v. Novartis Pharmas. Corp.*, Civil Action No. 19-21733 (SRC)(CLW) (D.N.J.); *Sun Pharma. Indus. Ltd. v. Pfizer, Inc.*, Civil Action No. 19-9330 (KM)(SCM) (D.N.J); *Sun Pharma. Indus., Ltd. v. Sungen Pharma LLC*, Civil Action No. 19-16404 (FLW)(LHG) (D.N.J.); *Galephar Pharma. Research, Inc. v. Upsher-Smith Laboratories, LLC*, Civil Action No. 19-2546 (MCA)(MAH) (D.N.J); *Dusa Pharmas., Inc. v. Biofrontera Inc*, Civil Action No. 23-20601 (RK)(JBD) (D.N.J.); *Sun Pharma. Indus. Ltd. v. Vistapharm, Inc.*, Civil Action No. 19-7536 (SRC)(CLW) (D.N.J.); *Cassiopea S.P.A. v. Aurobindo Pharma Ltd*., Civil Action No. 24-10734 (JKS)(JBC) (D.N.J.).

23. Alternatively, if Sun Ltd.'s connections with New Jersey, including its connections with Sun Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Sun Ltd. is not subject to jurisdiction in any state's courts of general

jurisdiction, and exercising jurisdiction over Sun Ltd. in New Jersey is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

24. For the above reasons, it would not be unfair or unreasonable for Sun Ltd. and/or Sun Inc. to litigate this action in this District, and the Court has personal jurisdiction over them here.

VENUE

25. Plaintiffs incorporate each of the proceeding paragraphs as if fully set forth herein.

26. Venue is proper in this district for Sun Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia,* Sun Inc. is a company with a principal place of business in New Jersey and is subject to personal jurisdiction in this judicial district.

27. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) with respect to Sun Ltd., at least because, on information and belief, Sun is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

BACKGROUND

28. Genentech is the holder of New Drug Application ("NDA") No. 203388 for ERIVEDGE® (vismodegib). Genentech's ERIVEDGE® is approved by FDA for the treatment of adults with basal cell carcinoma.

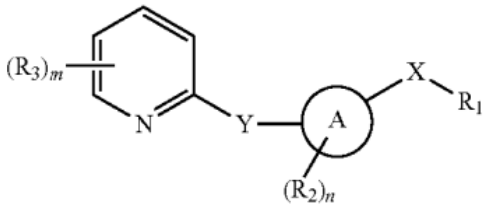
The '961 Patent

29. The '961 Patent, entitled "Pyridyl Inhibitors of Hedgehog Signalling" (Exhibit A), duly and legally issued on March 8, 2016.

30. Genentech and Curis are the owners and assignees of the '961 Patent.

31. ERIVEDGE® is covered by one or more claims of the '961 Patent, including at least claims 1, 37, 42, 66, and/or 93 of the '961 Patent, and the '961 Patent, among others, is listed in connection with ERIVEDGE® in the Orange Book.

32. Claim 1 of the '961 Patent claims:

> 1. A method of treating cancer in a mammal, comprising administering a compound of formula I:
>
> I
>
> 
>
>
> wherein
> A is a carbocycle or heterocycle;
> X is alkylene, $NR_4C(O)$, $NR_4C(S)$, $N(C(O)R_1)C(O)$, NR_4SO, NR_4SO2, $NR_4C(O)NH$, $NR_4C(S)NH$, $C(O)NR_4$, $C(S)NR_4$, NR_4PO or $NR_4PO(OH)$;
> Y is absent, CHR_4, O, S, SO, SO2 or NR_4;
> R_1 is selected from the group consisting of alkyl, a carbocycle or a heterocycle each of which is optionally substituted with hydroxyl, halogen, amino, carboxyl, amidino, guanidino, carbonyl, nitro, cyano, acyl, alkyl, haloalkyl, sulfonyl, sulfinyl, alkoxy, alkylthio, carbamoyl, acylamino, sulfamoyl, sulfonamide, a carbocycle or a heterocycle; wherein said amino, amidino, alkyl, acyl, sulfonyl, sulfinyl, alkoxy, alkylthio, carbamoyl, acylamino, sulfamoyl, sulfonamide, carbocycle and heterocycle substituent is optionally substituted with, halogen, haloakyl, hydroxyl, carboxyl, carbonyl, or an amino, alkyl, alkoxy, acyl, sulfonyl, sulfinyl, phosphinate, carbocycle or heterocycle that is optionally substituted with hydroxyl, carboxyl, carbonyl, amino, halogen, haloalkyl, alkyl, alkoxy, alkylthio, sulfonyl, sulfinyl, acyl, a carbocycle or a heterocycle;
> R_2 is halogen, hydroxyl, alkyl, acyl or alkoxy, wherein each alkyl, acyl and alkoxy is optionally substituted with hydroxyl, halogen, amino, nitro, alkyl, acyl, alkylsulfonyl or alkoxy;
> R_3 is halogen, hydroxyl, carboxyl, alkyl, acyl, alkoxy, alkoxycarbonyl, carbamoyl, alkylsulfide, sulfinyl, sulfonyl,

a carbocycle or a heterocycle wherein each alkyl, acyl, alkoxy, alkoxycarbonyl, carbamoyl, alkylsulfide, sulfinyl, sulfonyl, carbocycle and heterocycle is optionally substituted with hydroxyl, halogen, amino, nitro, alkyl, acyl, sulfonyl or alkoxy;

R_4 is H or alkyl;

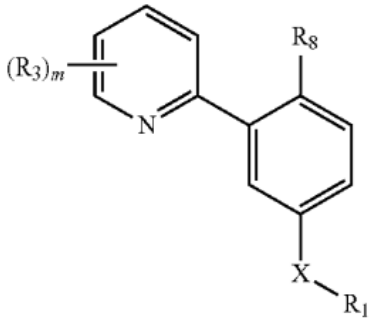
m is 0-3;

n is 0-3;

or a salt or solvate thereof.

33. Claim 37 of the ’961 Patent claims:

37. A method of treating cancer in a mammal, comprising administering a compound of the formula



wherein R3 is H or methyl,

R_8 is halogen or alkyl substituted with halogen;

X is $NR_4C(O)$,

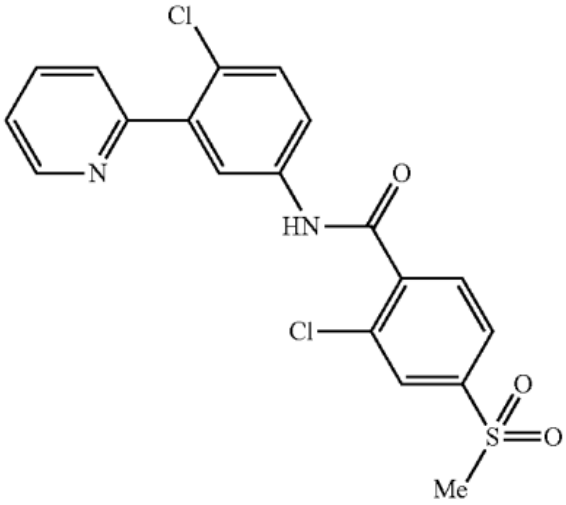
m is 0-3,

R_4 is H or alkyl, and

R^1 is aryl or heteroaryl, each of which is optionally substituted with hydroxyl, halogen, amino, carboxyl, amidino, guanidino, carbonyl, nitro, cyano, acyl, alkyl, haloalkyl, sulfonyl, sulfinyl, alkoxy, alkylthio, carbamoyl, acylamino, sulfamoyl, sulfonamide, a carbocycle or a heterocycle; wherein said amino, amidino, alkyl, acyl, sulfonyl, sulfinyl, alkoxy, alkylthio, carbamoyl, acylamino, sulfamoyl, sulfonamide, carbocycle and heterocycle substituent is optionally substituted with, halogen, haloakyl, hydroxyl, carboxyl, carbonyl, or an amino, alkyl, alkoxy, acyl, sulfonyl, sulfinyl, phosphinate, carbocycle or heterocycle that is optionally substituted with hydroxyl, carboxyl, carbonyl, amino, halogen, haloalkyl, alkyl, alkoxy, alkylthio, sulfonyl, sulfinyl, acyl, a carbocycle or a heterocycle, or a salt or solvate thereof.

34. Claim 42 of the ’961 Patent claims:

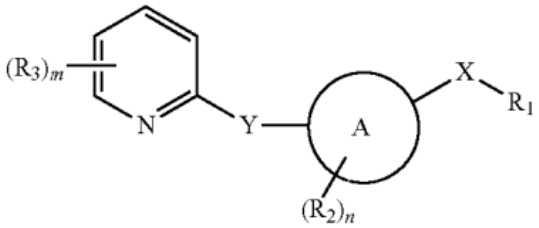
42. A method of treating cancer in a mammal, comprising administering a compound of the formula:



or a salt or solvate thereof.

35. Claim 66 of the ’961 Patent claims:

66. A method of treating cancer in a mammal, comprising administering a compound of the formula:



wherein

A is substituted benzene;

X is $NR_4C(O)$ or $NR_4C(S)$;

Y is absent;

R_1 is aryl or heteroaryl, each of which is optionally substituted;

R_2 is halogen, or alkyl substituted with halogen and an R_2 is in the o-position on said A benzene relative to pyridyl;

R_3 is halogen, hydroxyl, carboxyl, alkyl, acyl, alkoxy, alkoxycarbonyl, carbamoyl, alkylsulfide, sulfinyl, sulfonyl, a carbocycle or a heterocycle wherein each alkyl, acyl, alkoxy, alkoxycarbonyl, carbamoyl, alkylsulfide, sulfinyl, sulfonyl, carbocycle and heterocycle is optionally substituted with hydroxyl, halogen, amino, nitro, alkyl, acyl, sulfonyl or alkoxy;

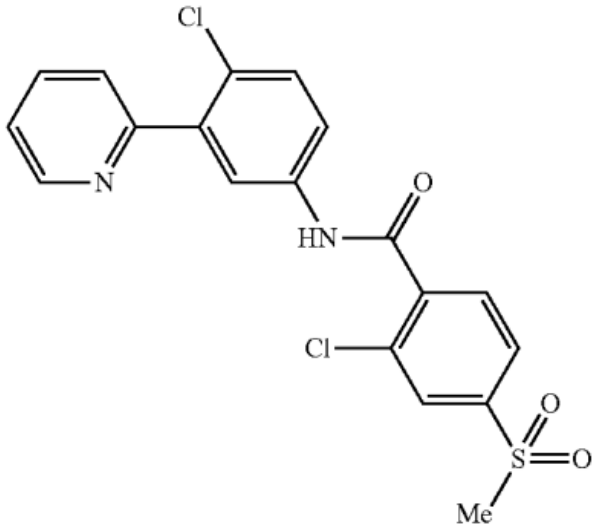
R_4 is H or alkyl;

m is 0-3;

n is 1-3;
or a salt or solvate thereof.

36. Claim 93 of the '961 Patent claims:

93. A method of treating basal cell carcinoma in a human, comprising orally administering an effective amount of a compound of the formula:



or a salt or solvate thereof.

INFRINGEMENT BY SUN

37. By letter ("Sun's Notice Letter"), Sun notified Genentech and Curis that it had filed a Paragraph IV Certification with respect to the '961 Patent and was seeking approval from the FDA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product prior to the expiration of the '961 Patent. On information and belief, Sun's ANDA contains a Paragraph IV Certification asserting that '961 Patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Sun's ANDA Product and/or that the '961 Patent is invalid.

38. The purpose of Sun's submission of Sun's ANDA was to obtain approval under the Federal Food, Drug and Cosmetic Act to engage in the commercial manufacture, use,

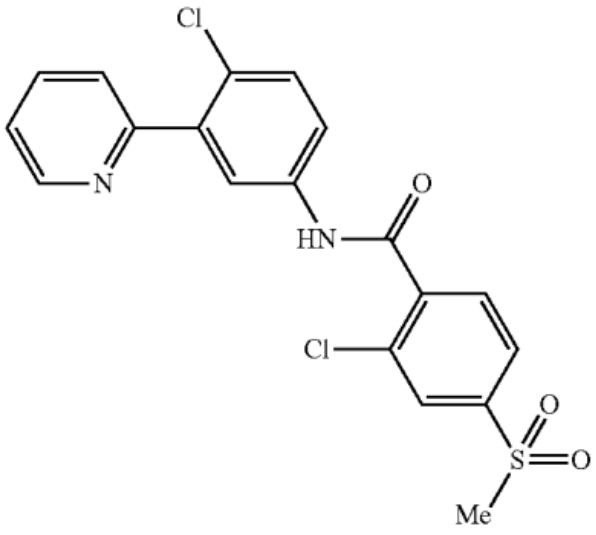
offer for sale, sale, and/or importation of Sun's ANDA Product prior to the expiration of the '961 Patent.

39. By filing or causing to be filed ANDA No. 220393 under 21 U.S.C. § 355 with a Paragraph IV Certification regarding the '961 Patent in order to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Sun's ANDA Product before the expiration of the '961 Patent, Sun committed an act of infringement of one or more claims of the '961 Patent under 35 U.S.C. § 271(e).

40. The use of Sun's ANDA Product is covered by one or more claims of the '961 Patent, including at least claims 1, 37, 42, 66, and/or 93.

41. On information and belief, the established name of the proposed drug product that is the subject of Sun's ANDA is "Vismodegib Capsules, 150 mg strength."

42. On information and belief, the active ingredient of Sun's ANDA Product is Vismodegib, which has the following chemical structure:



43. On information and belief, the proposed dosage strength of Sun's ANDA Product is 150 mg and the dosage form of the proposed product is a capsule intended to be administered orally.

44. On information and belief, Sun's ANDA Product, if approved by the FDA, is intended to be used, and will be used, for the treatment of basal cell carcinoma in a human via oral administration.

45. Sun's Notice Letter purported to provide Genentech with an Offer of Confidential Access ("OCA") to portions of Sun's ANDA. That offer, however, was subject to various unreasonably restrictive conditions.

46. Sun, in its Notice Letter, did not provide any substantive basis to contest the infringement of claims 1, 37, 42, 66, and/or 93 of the '961 Patent other than the alleged invalidity of those claims.

47. This action is being commenced before the expiration of forty-five days from the date of the receipt of Sun's Notice Letter.

COUNT I – INFRINGEMENT BY SUN OF THE '961 PATENT

48. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

49. Upon information and belief, Sun has acted with full knowledge of the '961 Patent and without a reasonable basis for believing that it would not be liable for infringement of the '961 Patent; active inducement of infringement of the '961 Patent; and/or contribution to the infringement of the '961 Patent, as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

50. Sun's submission of Sun's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA

Product prior to the expiration of the '961 Patent was an act of infringement of the '961 Patent under 35 U.S.C. § 271(e)(2)(A).

51. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product immediately and imminently upon FDA approval of Sun's ANDA.

52. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun's ANDA Product would infringe at least claims 1, 37, 42, 66, and/or 93 of the '961 Patent, recited above, either literally or under the doctrine of equivalents.

53. On information and belief, the use of Sun's ANDA Product in accordance with and as directed by Sun's proposed labeling for that product would infringe at least claims 1, 37, 42, 66, and/or 93 of the '961 Patent, recited above, either literally or under the doctrine of equivalents.

54. On information and belief, Sun, including by way of its proposed label for Sun's ANDA Product, plans and intends to, and will, actively induce infringement by instructing, recommending, encouraging, and/or suggesting to physicians and/or patients to infringe at least claims 1, 37, 42, 66, and/or 93 of the '961 Patent, when and after Sun's ANDA is approved.

55. On information and belief, Sun knows that Sun's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '961 Patent, that Sun's ANDA Product is not a staple article or commodity of commerce, and that Sun's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of the '961 Patent after approval of Sun's ANDA.

56. The foregoing actions by Sun constitute and/or will constitute infringement, active inducement of infringement, and contribution to the infringement of at least claims 1, 37, 42, 66, and/or 93 of the ’961 Patent.

57. On information and belief, Sun has acted with full knowledge of the ’961 Patent and without a reasonable basis for believing that it would not be liable for infringing the ’961 Patent, actively inducing infringement of the ’961 Patent, and contributing to the infringement of the ’961 Patent.

58. Plaintiffs will be substantially and irreparably damaged by infringement of the ’961 Patent. Plaintiffs have no adequate remedy at law.

59. Unless Sun is enjoined from infringing the ’961 Patent, actively inducing infringement of the ’961 Patent, and contributing to the infringement of the ’961 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT BY SUN OF THE ’961 PATENT

60. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

61. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Plaintiffs on one hand and Sun on the other regarding Sun’s infringement, active inducement of infringement, and contribution to the infringement of the ’961 Patent, and/or the validity of the ’961 Patent.

62. Upon information and belief, Sun has acted with full knowledge of the ’961 Patent and without a reasonable basis for believing that it would not be liable for infringement of the ’961 Patent; active inducement of infringement of the ’961 Patent; and/or contribution to the

infringement of the ’961 Patent, as evidenced, for example, by their knowledge of the Orange Book and submission of the Notice Letter.

63. On information and belief, Sun will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun’s ANDA Product with its proposed labeling upon FDA approval of Sun’s ANDA.

64. On information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sun’s ANDA Product would infringe at least claims 1, 37, 42, 66, and/or 93 of the ’961 Patent, recited above, either literally or under the doctrine of equivalents.

65. On information and belief, the use of Sun’s ANDA Product in accordance with and as directed by Sun’s proposed labeling for that product would infringe at least claims 1, 37, 42, 66, and/or 93 of the ’961 Patent, recited above.

66. On information and belief, Sun, including by way of its proposed label for Sun’s ANDA Product, plans and intends to, and will, actively induce infringement by instructing, recommending, encouraging, and/or suggesting to physicians and/or patients to infringe at least claims 1, 37, 42, 66, and/or 93 the ’961 Patent, when and after Sun’s ANDA is approved.

67. On information and belief, Sun knows that Sun’s ANDA Product and its proposed labeling are especially made or adapted for use in infringing the ’961 Patent, that Sun’s ANDA Product is not a staple article or commodity of commerce, and that Sun’s ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Sun plans and intends to, and will, contribute to infringement of at least claims 1, 37, 42, 66, and/or 93 of the ’961 Patent after approval of Sun’s ANDA.

68. The foregoing actions by Sun constitute and/or will constitute infringement of the '961 Patent, active inducement of infringement of the '961 Patent, and contribution to the infringement of at least claims 1, 37, 42, 66, and/or 93 of the '961 Patent.

69. On information and belief, Sun has acted without a reasonable basis for believing that it would not be liable for infringing, actively inducing infringement of, and contributing to the infringement of at least claims 1, 37, 42, 66, and/or 93 of the '961 Patent.

70. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Sun regarding whether Sun's manufacture, use, sale, offer for sale, or importation into the United States of Sun's ANDA Product with its proposed labeling according to Sun's ANDA will infringe, actively induce infringement of, and/or contribute to the infringement of at least claims 1, 37, 42, 66, and/or 93 of the '961 Patent, recited above, and whether said claims of the '961 Patent are valid.

71. Plaintiffs will be substantially and irreparably damaged by infringement of the '961 Patent. Plaintiffs have no adequate remedy at law.

72. The Court should declare that the commercial manufacture, use, sale, offer for sale and/or importation of Sun's ANDA Product with their proposed labeling, or any other Sun drug product that is covered by or whose use is covered by the '961 Patent, will infringe, induce infringement of, and contribute to the infringement of the '961 Patent, and that the claims of the '961 Patent are not invalid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Sun has infringed, will infringe, and will induce and contribute to infringement of the '961 Patent;

(b) A judgment pursuant to, among other things, 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval for Sun to make, use, offer for sale, sell, market, distribute, or import Sun's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '961 Patent, shall not be earlier than the expiration date of the '961 Patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A permanent injunction pursuant to, among other things, 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Sun, its officers, agents, servants, employees and attorneys, and all persons acting in concert with them, from making, using, selling, offering for sale, marketing, distributing, or importing Sun's ANDA Product, or any product the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '961 Patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '961 Patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that, prior to the expiration date of the'961 Patent, inclusive of any extension(s) and additional period(s) of exclusivity, the making, using, selling, offering for sale, marketing, distributing, or importing Sun's ANDA Product, or any product or compound the making, using, offering for sale, sale, marketing, distribution, or importation of which infringes the '961 Patent, will infringe, actively induce infringement of, and/or contribute to the infringement of the '961 Patent;

(e) A declaration that this case is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

Dated: June 13, 2025

ROBINSON MILLER LLC

s/ Keith J. Miller

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Attorneys for Plaintiffs Genentech, Inc. and Curis, Inc.

Local Rule 11.2 and 40.1 Certification

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, this matter is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Pursuant to Local Civil Rule 40.1, I hereby certify that, to the best of my knowledge, this matter does not relate to any case already or previously pending in the District of New Jersey.

Dated: June 13, 2025

ROBINSON MILLER LLC

s/ Keith J. Miller

Keith J. Miller
Bradley A. Suiters
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Attorneys for Plaintiffs Genentech, Inc. and Curis, Inc.

Local Rule 201.1 Certification

We hereby certify that the above captioned matter is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief.

Dated: June 13, 2025

ROBINSON MILLER LLC

s/ Keith J. Miller

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